SEP 2 6 2011

510(k) Summary

Applicant:	Spineology Inc. 7800 3rd Street N., Suite 600 Saint Paul, MN 55128 651-256-8500
Contact Person:	Bryan Becker
Date Prepared:	August 25, 2011
Trade Name:	Spineology PEEK Bullet Lumbar Interbody Fusion Device
Regulatory Classification:	Class II Medical Device, Product Code MAX, 21 CFR 888.3080 Intervertebral body fusion device
Predicate Device(s):	4CIS® PEEK PLIF Cage System from Solco, USA, Inc. Capstone Spinal System, Medtronic Sofamor Danek
Device Description:	The Spineology PEEK Bullet Lumbar Interbody Fusion Device is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The device is available in a range of lengths and heights and is made of PEEK-OPTIMA LT1 with Titanium markers. The device and associated instruments are provided non-sterile.
Indications for Use:	The Spineology PEEK Bullet Lumbar Interbody Fusion Device is an intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices may be implanted singly or in pairs via an open or a minimally invasive posterior or transforaminal approach. The Spineology PEEK Bullet Lumbar Interbody Fusion Device is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.
Summary of Technological Characteristics:	The device is shown to be substantially equivalent to the intended use, materials, configuration, and performance characteristics of the predicate products.
Testing	The Spineology PEEK Bullet Lumbar Interbody Fusion Device was tested in compliance with FDA's guidance document titled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device". Preclinical testing according to ASTM F2077 and ASTM

	F2267, including static compression, static compression shear, dynamic axial compression, and subsidence. Expulsion was also conducted. This testing demonstrated substantially equivalent performance characteristics to the identified predicate devices.
Conclusion:	The information submitted in this premarket notification supports a determination that the Spineology PEEK Lumbar Interbody Fusion Device is substantially equivalent in technological characteristics and intended use to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Spineology Inc.
% Mr. Bryan Becker
Clinical and Regulatory Affairs Manager
7800 3rd Street North, Suite 600
St. Paul, Minnesota 55128

SEP 26 2011

Re: K111880
Trade/Device Name: Spineology PEEK Bullet Lumbar Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: August 26, 2011
Received: August 29, 2011

Dear Mr. Becker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111880

Appendix D Indications for Use Form

Device Name: The Spineology PEEK Bullet Lumbar Interbody Fusion Device

Indications for Use:

The Spineology PEEK Bullet Lumbar Interbody Fusion Device is an intervertebral body fusion device indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

These devices may be implanted singly or in pairs via an open or a minimally invasive posterior or transforaminal approach.

The Spineology PEEK Bullet Lumbar Interbody Fusion Device is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared by the FDA for use in the lumbar spine.

Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111880